(1)

Supreme Court, U.S.
FILED

No. _____

081536 JUN 10 2009

In The OFFICE OF THE CLERK

Supreme Court of the United States

MARIA CARMEN PALAZZO, M.D., Ph.D., MMM,

Petitioner,

v.

THE UNITED STATES OF AMERICA,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

HERBERT V. LARSON, JR.
Counsel of Record
WILLIAM P. GIBBENS
SCHONEKAS, WINSBERG,
EVANS & MCGOEY, L.L.C.
650 Poydras Street, Suite 2105
New Orleans, Louisiana 70130
(504) 680-6050

Attorneys for Petitioner
Maria Carmen Palazzo

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTION PRESENTED

To regulate clinical testing in the pharmaceutical industry, Congress enacted 21 U.S.C. § 355(i), which requires a drug manufacturer and the clinical trial sponsor to keep records and file reports directly with the Secretary of Health and Human Services. This statute does not impose any record-keeping requirements on clinical investigators, and it specifically exempts clinical investigators from any direct reporting requirements. *See* 21 U.S.C. § 355(i)(4). To ensure compliance with its regulatory scheme, Congress criminalized the failure to "establish or maintain any record, or make any report, required under . . . 355(i)." *See id.* § 331(e). Notwithstanding the express language of the statute excluding clinical investigators, the United States Court of Appeals for the Fifth Circuit reinstated a criminal prosecution against Dr. Maria Carmen Palazzo, a clinical investigator, who had been indicted for "fail[ure] to prepare and maintain records required under 21 U.S.C. § 355(i) and 21 C.F.R. § 312.62(b)."

The question presented is whether the Fifth Circuit erroneously held, in conflict with the decisions of the Eighth and Ninth Circuit Courts of Appeals, that in 21 U.S.C. § 355(i), Congress delegated to the Secretary of Health and Human Services the authority to create criminally enforceable regulations governing physician clinical investigators.

PARTIES TO THE PROCEEDINGS

1. Maria Carmen Palazzo
2. The United States of America

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDINGS	ii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
STATEMENT OF JURISDICTION	1
RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS	2
I. Constitutional Provisions	2
II. Statutory Provisions	2
STATEMENT OF THE CASE	7
I. The Proceedings In The District Court	10
II. The Opinion Of The Court Of Appeals	13
REASONS FOR GRANTING THE WRIT	15
I. The Courts Of Appeals Are Divided As To Whether Clinical Investigators Can Be Prosecuted Under 21 U.S.C. § 331(e) For Violations Of 21 U.S.C. § 355(i)	15
II. The Fifth And Eighth Circuits Have Ignored The Basic Structure Of The Congressional Regulatory Scheme For Clinical Trials Of Drugs, And Have Misapplied This Court's Opinion In *Touby*	20

TABLE OF CONTENTS – Continued

Page

A. In Enacting 21 U.S.C. § 355(i) Congress Did Not Delegate To The Secretary The Authority To Impose Criminal Sanctions On Anyone – Drug Manufacturers, Sponsors, Or Clinical Investigators 20

B. Any "Intelligible Principle" That Can Be Found In 21 U.S.C. § 355(i) Would Preclude The Prosecution Of Clinical Investigators 22

III. This Case Presents An Issue Of National Importance Because Of Its Potential Impact On Thousands Of Physicians 25

CONCLUSION 26

APPENDIX

U.S. Court of Appeals for the Fifth Circuit Opinion (February 6, 2009) ..... App. 1

U.S. District Court for the Eastern District of Louisiana Order and Reasons (October 24, 2007) ..... App. 19

U.S. Court of Appeals for the Fifth Circuit Denial of Rehearing En Banc (March 20, 2009) ..... App. 46

TABLE OF AUTHORITIES

Page

CASES

Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984) 9, 18

Gonzales v. Oregon, 546 U.S. 243 (2006) 19

Mistretta v. United States, 488 U.S. 361 (1989) 22

Touby v. United States, 500 U.S. 160 (1991) ... 8, 20, 22

United States v. Garfinkel, 29 F.3d 451 (8th Cir. 1994) 9, 18, 19

United States v. Smith, 740 F.2d 734 (9th Cir. 1984) 8, 15, 18, 24

CONSTITUTIONAL PROVISIONS

U.S. Const. art. I, § 1 2

U.S. Const. amend. V 2

STATUTES

21 C.F.R. § 312.1(c) 8

21 C.F.R. § 312.62(b) 10, 14, 20

18 U.S.C. § 1347 10

21 U.S.C. § 331 11

21 U.S.C. § 331(e) ..... *passim*

21 U.S.C. § 333(a)(1) 14

21 U.S.C. § 333(a)(2) 10, 11

21 U.S.C. § 333(b) 15

TABLE OF AUTHORITIES – Continued

Page

21 U.S.C. § 355(i) ..... *passim*

21 U.S.C. § 355(i)(1) 2, 21

21 U.S.C. § 355(i)(1)(C) 3, 23

21 U.S.C. § 355(i)(3) 5

21 U.S.C. § 355(i)(4) 6, 7, 23

28 U.S.C. § 1254(1) 1

RULES

Supreme Court Rule 13.1 2

Supreme Court Rule 13.3 2

OTHER AUTHORITIES

William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from* Chevron *to* Hamdan, 96 Geo. L.J. 1083 (2008) 19

S. Rep. No. 1744, *reprinted in* 1962 U.S. Code Cong. & Ad. News 2884 24

PETITION FOR A WRIT OF CERTIORARI

Petitioner Maria Carmen Palazzo respectfully requests that the Court issue a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit issued in this case on February 6, 2009.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-18) is reported at 558 F.3d 400 (5th Cir. 2008). The opinion of the court of appeals denying Palazzo's petition for rehearing en banc (Pet. App. 46-47) is unreported. The district court's opinion dismissing the 15 criminal counts based on alleged violations of 21 U.S.C. §§ 355(i) and 331(e) (Pet. App. 19-45) is published at 2007 WL 3124697 (E.D.La. Oct. 24, 2007).

STATEMENT OF JURISDICTION

On October 10, 2007, in response to a motion by Palazzo to dismiss counts 41-55 of the superseding indictment that had been filed against her, the district court entered an order dismissing those counts. The Government timely appealed to the United States Court of Appeals for the Fifth Circuit. On February 6, 2009, that court reversed the district court. Palazzo timely filed a petition for rehearing en banc, which was denied on March 20, 2009. This Court has jurisdiction over this petition pursuant to 28 U.S.C.

§ 1254(1), and this petition is timely under Supreme Court Rules 13.1 and 13.3.

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

I. Constitutional Provisions

The Vesting Clause of the United States Constitution, U.S. Const. art. I, § 1, provides, in pertinent part:

> All legislative Powers herein granted shall be vested in a Congress of the United States. . . .

The Fifth Amendment to the United States Constitution, U.S. Const. amend. V, provides, in pertinent part:

> No person shall . . . be deprived of life, liberty, or property without due process of law. . . .

II. Statutory Provisions

21 U.S.C. § 355(i), Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary, provides:

> (1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and

experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon –

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of

such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section; and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including –

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)

(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that –

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

21 U.S.C. § 331(e), provides as follows:

The following acts and the causing thereof are prohibited:

> **(e)** The refusal to permit access to or copying of any record as required by section 350a, 350c, 350e, 354, 360bbb-3, 373, 374(a), 379aa, or 379aa-1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l) or (m), 360ccc-1(i), 360e(f), 360i, 360bbb-3, 379aa, or 379aa-1 of this title, or the refusal to permit access to or verification or copying of any such required record.

STATEMENT OF THE CASE

Every year in the United States, thousands of physicians, acting as clinical investigators, conduct more than 80,000 clinical trials for drug manufacturers and other entities willing to sponsor such drug trials. To regulate this critical facet of the pharmaceutical industry, Congress created the scheme set forth in 21 U.S.C. § 355(i).

Put most simply, this statute requires manufacturers and sponsors to keep certain data and records, and to make reports directly to the Secretary of the Department of Health and Human Services (DHHS). The failure to do so may result in a manufacturer or a sponsor losing the exemption [from all other portions of the statute] necessary to conduct such trials, or it may result in a criminal prosecution under 21 U.S.C. § 331(e). In enacting section 355(i), Congress specifically provided, subsection 355(i)(4),

that "[n]othing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs."

And while section 355(i) does give the Secretary of the DHHS the authority to promulgate certain regulations, that authority is limited to promulgating regulations that *exempt* persons from the operation of "the foregoing subsections." Nowhere in the statute is the Secretary given either the authority to promulgate criminal regulations imposing affirmative duties, or the Congressional guidance that would be necessary for creating such criminal regulations, guidance that this Court found to be constitutionally necessary in its decision in *Touby v. United States*, 500 U.S. 160 (1991).

Nevertheless, in *Palazzo,* the Fifth Circuit found that a purely civil regulation, 21 C.F.R. § 312.62(b), which requires a clinical investigator to "prepare and maintain adequate and accurate case histories" – on pain of suspension from participation in clinical trials, but nothing more – could be made criminal first by incorporating it into section 355(i), and then by incorporating it into section 331(e).

The Fifth Circuit's opinion is in flat contradiction to that of the Ninth Circuit in *United States v. Smith*, 740 F.2d 734, 739 (9th Cir. 1984), which expressly held that "Congress did not provide sufficient guidance for the promulgation of regulations which would subject investigators to criminal liability for

noncompliance. Moreover, even if Congress had provided guidelines for such regulations, the regulatory language falls short of justifying the imposition of criminal sanctions for noncompliance."

The opinion of the Fifth Circuit in *Palazzo* also is in contradiction to that of the Eighth Circuit in *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994). Although the *Garfinkel* court did find that section 355(i) authorized the Secretary of the DHHS to promulgate criminally enforceable regulations, it could make that finding only by giving *Chevron* deference to the Secretary's interpretation of section 355(i). *Id.* at 456 (*citing Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984) (setting forth the legal test for determining whether to grant deference to a government agency's interpretation of its own statutory mandate)). Regretfully, the Eighth Circuit completely overlooked the fact that there is no *Chevron* deference in criminal cases.

In short, with its decision in *Palazzo*, the Fifth Circuit has created a new crime that will affect thousands of physicians, and that could upset the entire Congressional regulatory scheme for clinical trials. Worse, as will be shown below, the Fifth Circuit has done so in a way that flies in the face of straightforward statutory language and unambiguous case law from this Court.

I. The Proceedings In The District Court

On August 25, 2005, four days before Hurricane Katrina, a grand jury sitting in the Eastern District of Louisiana returned a 17-count indictment against Dr. Maria Carmen Palazzo, charging her with two counts of health care fraud (18 U.S.C. § 1347), and 15 counts of violating the record-keeping requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §§ 331(e), 333(a)(2)). Following delays caused by Hurricane Katrina, and motions relating to the first indictment, a superseding indictment was returned in June 2007, charging Dr. Palazzo with 40 counts of health care fraud, and the same 15 counts of violating the record-keeping requirements of the FDCA.

In both the original and superseding indictments, the Government alleged that in October 2000, SmithKline Beecham, d/b/a GlaxoSmithKline (SKB), "a pharmaceutical company engaged in developing, testing, and marketing pharmaceutical products including Paroxetine, also known as 'Paxil,' * * * hired MARIA CARMEN PALAZZO, a licensed psychiatrist practicing medicine in New Orleans, to participate as a Clinical Investigator in a study involving Paxil. . . ." The purpose of the study was "to evaluate the efficacy and safety of Paxil in children and adolescents with Obsessive-Compulsive Disorder (OCD)."

It was alleged that Dr. Palazzo, "with intent to defraud and mislead, failed to prepare and maintain records required under 21 U.S.C. § 355(i), and 21

C.F.R. § 312.62(b), to-wit, adequate and accurate case histories on each individual administered the investigational drug or employed as a control in the . . . investigation." The common inaccuracy alleged for each case history was that the subject was not qualified to participate in the study because the subject was not suffering from OCD.

Between the original indictment and the superseding indictment, Dr. Palazzo moved to dismiss the 15 counts charging violations of the record-keeping requirements of the FDCA, sections 331(e) and 333(a)(2), on the grounds that the statute in question did not authorize the imposition of criminal liability upon a *clinical investigator* for failing to maintain accurate records.

More specifically, Dr. Palazzo argued:

1. In these counts, she was charged with violating 21 U.S.C. §§ 331(e) and 333(a)(2);

2. 21 U.S.C. § 331 states that "[t]he following acts and the causing thereof are prohibited: (e) . . . the failure to establish or maintain any record, or make any report, required under section . . . 355(i)."

3. Section 355(i) imposes record-keeping and reporting requirements on the *manufacturer*, or the *sponsor* of the investigation of such drug, but *not* on the clinical investigators.

4. Consequently, since Dr. Palazzo did not fall within the plain language of the statute, she was not subject to criminal liability.

Following oral argument on the motion, the district court dismissed these 15 counts. In its opinion, the district court looked first to the plain language of the statutes in question, then to the constitutional issues, and then finally to the relevant case law, and concluded as follows:

> The court agrees with the reasoning of the Ninth Circuit in *Smith* that § 355(i) does not authorize criminal penalties for violations by clinical investigators in maintaining adequate and accurate records. Congress did not grant broad authority, but specifically singled out manufacturers and sponsors, not clinical investigators. Unlike the decision in *Garfinkel*, the court concludes that nothing in the language of § 355(i) provides sufficient guidelines regarding clinical investigators to serve as an intelligible principle to which the HHS or the FDA is directed to conform. The statute falls short of the multiple restrictions or mandatory requirements of *Touby* with regard to any party other than the manufacturer or the sponsor of the investigation. Although the amended, post-*Smith* regulations impose responsibility on clinical investigators to maintain adequate and accurate records, the focus of the constitutional inquiry is not directed to the amended regulations, but to the language of § 355(i) and whether the

> statute is specific as to the restraints on imposing criminal conduct. Accordingly, the court concludes that Congress did not specifically authorize regulations giving rise to criminal liability under § 355(i), and the motion to dismiss counts 41-55 of the superseding indictment is granted.

Pet. App. 35-36. Thereafter, the Government appealed to the Fifth Circuit.

II. The Opinion Of The Court Of Appeals

On appeal, the Government made two arguments: (1) that section 355(i) authorizes criminally enforceable regulations requiring clinical investigators to maintain adequate and accurate records; and (2) that the statute contains sufficient guidelines and is fully consistent with the non-delegation doctrine.

Conversely, Palazzo contended that section 355(i) did *not* authorize the creation of criminally enforceable regulations for clinical investigators, because under its plain language, the statute only permits the Secretary to create *exemptions* from the overarching regulatory scheme approved by Congress. The FDA is permitted to condition the granting of those exemptions upon compliance with regulations promulgated by the Secretary, but those conditions only may be imposed upon those entities with a direct reporting relationship to the FDA – the manufacturers of the new drug or sponsors of the investigation of the new drug. Palazzo argued that these are the only entities that

are required to establish and maintain records for the Secretary, and the only entities required to report to the Secretary.

In response to the arguments of the parties, the Fifth Circuit noted that "[t]he Ninth Circuit, Eighth Circuit, and district court each used different legal frameworks to analyze the question of whether § 355(i) allows the FDA to criminalize conduct of clinical investigators who fail to adhere to the FDA's regulations regarding record-keeping and reporting requirements." Pet. App. 6. After reviewing the decisions of all three, the Fifth Circuit proceeded to use a fourth framework, one shaped by the court's conclusion that "the issue on appeal requires this court to engage *only* in statutory interpretation." Pet. App. 11.

Having concluded implicitly that all of its predecessors were in error, the Fifth Circuit first found that Dr. Palazzo was required to keep records, by virtue of 21 C.F.R. § 312.62(b), then found that section 355(i) allows the Secretary to establish reporting requirements, and that the provisions of 21 C.F.R. § 312.62(b) properly are considered to be "'required' record-keeping and reporting requirements." Because the record-keeping and reporting was "required," criminal liability would attach by virtue of 21 U.S.C. § 331(e). In the words of the Fifth Circuit:

> Thus, reviewing § 312.62(b) in conjunction with §§ 355(i), 331(e), and 333(a)(1) makes it apparent that the scope of the statute allows

> clinical investigators to be subjected to criminal liability.

Pet. App. 17. The Court of Appeals then reversed the district court, and remanded the matter for further proceedings.

REASONS FOR GRANTING THE PETITION

I. The Courts Of Appeals Are Divided As To Whether Clinical Investigators Can Be Prosecuted Under 21 U.S.C. § 331(e) For Violations Of 21 U.S.C. § 355(i).

The question raised in this petition first arose 25 years ago in *United States v. Smith,* 740 F.2d 734 (9th Cir. 1984). In *Smith*, defendants were charged "with failure to maintain accurate drug testing records in violation of 21 U.S.C. §§ 331(e), 333(b) and 355(i). Specifically, the indictment alleged that the defendants had failed to maintain accurate records by placing falsified and fraudulent data, including false consent forms, in patient files." *Id.* at 735-36.

As in Palazzo's case, the defendant, a physician clinical investigator, moved to dismiss these counts in the indictment. And as in this case, the Government appealed the district court's ruling dismissing the counts. Unlike the Fifth Circuit, however, the Ninth Circuit affirmed the district court, reasoning as follows:

Although the statute expressly authorizes regulations which impose affirmative duties on manufacturers and the sponsors of clinical investigations, we are reluctant to read the statute as authorizing criminal penalties for the violation of any regulation promulgated pursuant to the statute's *general* authorizing language. In creating the obligation to maintain drug testing records, Congress expressly imposed the burden on manufacturers and sponsors. § 355(i)(3). The government asks that we extend the statutory obligation to include clinical investigators pursuant to the statute's general regulatory authority which allows the Secretary to establish "other conditions relating to the protection of public health" before exempting manufacturers from the statute's basic drug approval application requirements. § 355(i). Such general authorizing language, however, is insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability. Executive agencies have the authority to establish regulations which are enforced by criminal penalties only when Congress has provided "sufficient guidelines and standards for the exercise of the authority."

Moreover, even if Congress had provided standards for extending the recordkeeping requirement to investigators by regulation, the regulatory language falls short of imposing an explicit affirmative duty on the investigators to maintain accurate records.

The regulations do not make it clear that the investigator violates the statute by failing to submit accurate test data to the sponsor. Absent such a clear articulation of duty, we are not prepared to fasten criminal liability to the investigator who fails to fulfill his or her obligation to the sponsor.

Generally, when a criminal statute is ambiguous, courts are reluctant to find criminal liability for those activities which are only questionably within its ambit. This principle of lenity is rooted in two major concerns. First, it ensures that there is fair warning "of what the law intends to do if a certain line is passed." Second, because of the serious nature of criminal sanctions "and because criminal punishment usually represents the moral condemnation of the community, legislatures and not courts should define criminal activity." Adhering to the principle embodying these concerns, we are unwilling to find criminal liability here.

* * *

The statute and regulations at issue here do not impose a clear duty on investigators to maintain accurate records. They only impose affirmative duties on drug manufacturers and the sponsors of clinical investigations. If the FDA discovers that an investigator has falsified information in forms submitted to the sponsor, the FDA, pursuant to the regulations, may conduct an administrative hearing and revoke the investigator's entitlement to work with

> investigational drugs. 21 C.F.R. § 312.1(c). Under these circumstances, we cannot fairly read the pertinent statute and regulations to attach criminal liability to these defendants.

Smith, 740 F.2d at 737-39 (internal citations and footnote omitted).

Ten years later, the issue returned in *United States v. Garfinkel,* 29 F.3d 451 (8th Cir. 1994), in which the Government was again appealing the dismissal of criminal charges brought against a physician clinical investigator under 21 U.S.C. §§ 331(e) and 355(i).

In *Garfinkel,* the Eighth Circuit found that the question of criminal liability comprised two separate issues: (1) whether section 355(i) *authorized* the FDA regulations at issue; and (2) whether section 355(i) provided *sufficient guidance* for the issuance of clinical investigator regulations that provide for criminal penalties. *Id.* at 454-55. As the Court noted, "[t]he first argument raises a question of statutory construction, while the second argument raises a question of constitutional dimension, namely, the effect of the nondelegation doctrine." *Id.* at 455.

The Eighth Circuit found that section 355(i) authorized the FDA regulations at issue. Significantly, and unfortunately, in so finding, the Eighth Circuit failed to draw a distinction between the authority to issue civil regulations, and the authority to issue criminally enforceable regulations. Had it done so, it never would have conducted a *Chevron*

deference analysis expressly and explicitly relying on deference to the FDA's interpretation of the statute in question. *Id.* at 456. *Chevron* deference is not given to criminal statutes because of the very basic principle, grounded in due process, that there is no deference to the Government's interpretation of a statute in criminal cases – the rule of lenity applies, not the *Chevron* rule of substantial deference to an agency's interpretation of a statute. *See Gonzales v. Oregon*, 546 U.S. 243, 264 (2006). *See also* William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from* Chevron *to* Hamdan, 96 Geo. L.J. 1083, 1115-16 (2008) (describing the policy in criminal cases as "anti-deference," and noting that one "interconnected thread" for the anti-deference policy is the rule of lenity).

Thus, the Eighth Circuit's labored conclusion "that the standards enunciated by the Act, along with judicial review and the procedural requirements dictated by the APA, impose sufficient restraints upon FDA to satisfy the constitutional concerns underlying the nondelegation doctrine" is not only in contradiction to the Ninth and Fifth Circuits, it is just plain wrong. *Garfinkel*, 29 F.3d at 459.

In stark contrast to the approach of the Eighth Circuit, with its lengthy delegation doctrine analysis, is the one used by the Fifth Circuit, which concluded that it did not need to address the doctrine at all, because Palazzo "conceded" that the regulation at issue was a valid one. The Fifth Circuit has not only

misstated the nature of Palazzo's "concession," its entire approach turns the delegation doctrine upside down.

Palazzo contended from the outset that the Secretary had no authority to create *criminally* enforceable regulations. Her only "concession" – one made at oral argument – was that 21 C.F.R. § 312.62, which requires clinical investigators to "prepare and maintain adequate and accurate cases histories," was a valid *civil* regulation. But what is most disconcerting, and most worthy of this Court's attention, is the Fifth Circuit's creation of a criminal regulatory scheme, the validity of which depends upon concessions from those affected by it. This would be risible, were the consequences not so severe.

II. The Fifth And Eighth Circuits Have Ignored The Basic Structure Of The Congressional Regulatory Scheme For Clinical Trials Of Drugs, And Have Misapplied This Court's Opinion In *Touby*.

A. In Enacting 21 U.S.C. § 355(i) Congress Did Not Delegate To The Secretary The Authority To Impose Criminal Sanctions On Anyone – Drug Manufacturers, Sponsors, Or Clinical Investigators

Even a casual reading of 21 U.S.C. § 355(i) compels the conclusion that the only power Congress delegated to the Secretary in that statute is the power to create exemptions from existing laws

enacted by Congress – not the affirmative power to create crimes:

> **(1)** *The Secretary shall promulgate regulations for exempting* from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, *provide for conditioning such exemption upon* –

21 U.S.C. § 355(i)(1) (emphasis added). At the risk of sounding simplistic, it is self-evident that regulations creating exemptions from "the operation of the foregoing subsections" are necessarily very different – both conceptually and legally – from regulations imposing criminal liability. The former allow one to escape the application of a law, the latter compel compliance with it.

Nevertheless, both the Fifth and Eighth Circuits have found that, notwithstanding the plain language of the statute, the Secretary of DHHS has the Congressional authority to create criminally enforceable regulations, and that such regulations can be extended to clinical investigators.

B. Any "Intelligible Principle" That Can Be Found In 21 U.S.C. § 355(i) Would Preclude The Prosecution Of Clinical Investigators

Unquestionably, Congress may delegate the task of "filling in the details" of a criminal statute, and that such a delegation may be quite broad. In the words of this Court in *Touby v. United States*:

> We have long recognized that the nondelegation doctrine does not prevent Congress from seeking assistance, within proper limits, from its coordinate Branches. Thus, Congress does not violate the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors. So long as Congress "lay[s] down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power."

500 U.S. 160, 165 (1991) (internal citations omitted).

The Court has summarized the "intelligible principle" test in these terms: a delegation of legislative power will be "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Mistretta v. United States*, 488 U.S. 361, 372-73 (1989).

But even if it can be assumed that Congress intended to delegate to the Secretary the power to

create criminally enforceable regulations, the statute on its face would limit the application of those regulations to drug manufacturers and the sponsors of clinical trials.

First, section 355(i) requires no record or report from any clinical investigator. As the Fifth Circuit acknowledged, "[o]n its face, § 355(i) does not provide criminal liability for sponsors and manufacturers of investigational drug studies or clinical investigators. [ ] In addition, § 355(i) does not contain an explicit requirement governing the conduct of clinical investigators." Pet. App. 15. In fact, they are explicitly *excluded* from its reporting requirements: "Nothing in this subsection shall be construed to *require* any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs." 21 U.S.C. § 355(i)(4).

Second, the statute requires no record keeping by clinical investigators. The only section of the statute to address record keeping, section 355(i)(1)(C), requires "the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug."

Any fair reading of this statute, and any reasonable interpretation of this regulatory scheme can lead to only one conclusion: Congress gave the Secretary of the DHHS the power to regulate the conduct of drug manufacturers and sponsors of investigations by giving the Secretary the power to

grant *exemptions* from what would otherwise be criminal conduct; and it gave the Secretary the power to condition those exemptions by making the manufacturers and sponsors meet certain record-keeping and reporting requirements. And for good measure, *Congress*, not the Secretary, criminalized the failure to satisfy those requirements.

Congress expressly rejected the creation of a direct reporting relationship between clinical investigators and the Secretary, and with it, the imposition of criminal consequences on clinical investigators. The legislative history of the statute completely supports that contention:

> Moreover, we note that the Senate Report accompanying the adoption of § 355 indicates that Congress was primarily concerned with the lack of adequate information from drug *manufacturers* regarding the use of experimental drugs. The proposed legislation was designed to "permit the Secretary to issue regulations requiring that *manufacturers* keep records and make reports of such investigations and clinical experience" S. Rep. No. 1744, *reprinted in* 1962 U.S. Code Cong. & Ad. News 2884, 2891 (emphasis added). The legislative history does not indicate that Congress was attempting to impose affirmative responsibilities on investigators working at the manufacturer's direction.

Smith, 740 F.2d at 739.

III. This Case Presents An Issue Of National Importance Because Of Its Potential Impact On Thousands Of Physicians.

It goes without saying that the process of determining the safety and efficacy of drugs must be regulated. Unquestionably, DHHS is the appropriate agency to handle such regulation. But with regard to clinical trials, Congress has limited such regulation by the DHHS to the imposition of reporting and record-keeping requirements upon drug manufacturers and sponsors only. It is the courts, acting at the behest of the DHHS, that have expanded those requirements.

The Congressional limitation is not illogical – Congress well may have believed that attempting to regulate physicians conducting such clinical trials was tantamount to the regulation of the practice of medicine, a matter that has traditionally been left to the States. But if the DHHS now is going to enter that field and regulate physicians conducting clinical trials by means of criminal sanctions, the authority to do so should be unmistakable – not the inconsistent and confused product of 25 years of litigation in three different circuits.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

New Orleans, Louisiana, this 10th day of June, 2009.

Respectfully submitted,

HERBERT V. LARSON, JR.
Counsel of Record
WILLIAM P. GIBBENS
SCHONEKAS, WINSBERG, EVANS & MCGOEY, L.L.C.
650 Poydras Street, Suite 2105
New Orleans, Louisiana 70130
(504) 680-6050

Attorneys for Petitioner
Maria Carmen Palazzo

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 07-31119

UNITED STATES OF AMERICA

Plaintiff-Appellant

v.

MARIA CARMEN PALAZZO, M.D., PH.D., MMM

Defendant-Appellee

Appeal from the United States District Court
for the Eastern District of Louisiana

(Filed Feb. 6, 2009)

Before REAVLEY, STEWART and OWEN, Circuit Judges.

CARL E. STEWART, Circuit Judge:

Defendant-Appellee Maria Carmen Palazzo, M.D., Ph.D., MMM ("Dr. Palazzo"), a licensed medical doctor specializing in psychiatry, was a Medicare provider authorized to submit bills for reimbursement for certain medical services provided to eligible Medicare beneficiaries. Dr. Palazzo entered into contracts with SmithKline Beecham, Corporation ("SKB") to carry out clinical drug studies evaluating the efficacy

and safety of Paxil in children and adolescents. She failed to comply with the study protocol and to review personally all information regarding the study subjects. Plaintiff-Appellant, the United States ("the Government"), brought charges against Dr. Palazzo for health care fraud and failure to maintain records of the clinical drug studies in violation of 21 U.S.C. § 355(i). The grand jury returned a superseding indictment charging Dr. Palazzo with forty counts of health care fraud and fifteen counts for violations of § 355(i) and 21 C.F.R. § 312.64(b). The district court dismissed the § 355(i) counts, forty-one through fifty-five of the superseding indictment. On appeal, the Government challenges the dismissal of those counts. For reasons discussed below, we REVERSE and REMAND.

I. FACTUAL AND PROCEDURAL BACKGROUND

Dr. Palazzo was a duly licensed Medical Doctor (M.D.) specializing in psychiatry, with offices located in New Orleans, Louisiana. Dr. Palazzo served as a Medicare provider authorized to submit bills for reimbursement for certain medical services provided to eligible Medicare beneficiaries.

On July 5, 2000, and July 27, 2001, Dr. Palazzo entered into professional services agreements with Touro Infirmary ("Touro") to provide consultation services for the Adult Psychiatric Programs at Touro. On June 1, 2002, and June 1, 2003, Dr. Palazzo and

Touro entered into an agreement for Dr. Palazzo to serve as medical director for Touro's inpatient Adult Psychiatric and Adult Partial Hospitalization Programs. Each agreement was for a one-year term and provided compensation at a rate of $150 per hour up to $144,000 per year. The agreements expressly required Dr. Palazzo to provide a written monthly statement documenting the amount of time worked and detailing services rendered.

Touro sent its Medicare Part A claims to Mutual of Omaha, which received, settled, and paid the claims pursuant to a contract with the Centers for Medicare and Medicaid Services, an agency of the United States Department of Health and Human Services. Dr. Palazzo submitted Medicare Part B bills to Blue Cross/Blue Shield.

Apart from her consultation work at Touro, SKB hired Dr. Palazzo on October 31, 2000, as a clinical investigator to carry out clinical studies to evaluate the efficacy and safety of Paxil in children and adolescents with obsessive-compulsive disorder. Dr. Palazzo received $5,410 for each subject who completed the study and agreed to review personally all case report forms regarding each study subject. On February 9, 2001, SKB contracted with Dr. Palazzo to participate as a clinical investigator to assess the long term safety of Paxil in children and adolescents with major depressive disorder or obsessive-compulsive disorder. Dr. Palazzo received $5,020 for each subject who completed the study, and she agreed to comply with the study protocol and personally review all information

regarding the study subject. Dr. Palazzo did not comply with the criteria to provide satisfactory research records, and her contracts to participate in the drug studies were terminated.

On August 25, 2005, a grand jury indicted Dr. Palazzo with two counts of health care fraud and fifteen counts of failure to maintain records of the clinical drug studies in violation of 21 U.S.C. § 355(i). On January 14, 2007, a grand jury returned a superseding indictment charging Dr. Palazzo with forty counts of health care fraud and fifteen counts of violations of § 355(i) and 21 C.F.R. § 312.62(b).[1]

This appeal concerns the fifteen counts for violating § 355(i) and 21 C.F.R. § 312.62(b) for failure to properly prepare and maintain records with intent to defraud and mislead. Counts forty-one through fifty-two include allegations of inaccuracies in Dr. Palazzo's psychiatric evaluations of subjects participating in the Paxil studies. These counts allege that Dr. Palazzo's psychiatric evaluations stated that subjects suffered from disorders when the subjects had not been diagnosed with the disorders. Counts fifty-three through fifty-five allege that Dr. Palazzo reported examining a subject, when in fact she did not personally examine the subject.

---

[1] 21 U.S.C. § 331 sets out certain prohibited acts, and § 331(e) prohibits "the failure to establish or maintain any record, or make any report, required under section . . . 355(i)."

The district court granted Dr. Palazzo's motion to dismiss counts forty-one through fifty-five based on the nondelegation doctrine. The district court determined that § 355(i) does not permit the U.S. Food and Drug Administration ("FDA") to promulgate regulations making clinical investigators criminally liable for failure to properly keep records and report accurate information. In making this determination, the district court analyzed two cases that previously dealt with the application of § 355(i) to clinical investigators, *United States v. Smith,* 740 F.2d 734 (9th Cir. 1984) and *United States v. Garfinkel,* 29 F.3d 451 (8th Cir. 1994). The district court adopted the reasoning of *Smith,* and dismissed the counts based on the nondelegation doctrine. *United States v. Palazzo,* No. 05-0266, 2007 WL 3124697, 2007 U.S. Dist. LEXIS 78986 (E.D. La. Oct. 24, 2007).

II. STANDARD OF REVIEW

A constitutional challenge to a federal statute is a question of law that this court reviews *de novo. United States v. Pierson,* 139 F.3d 501, 503 (5th Cir. 1998) (citation omitted). Issues of statutory interpretation are also reviewed *de novo. United States v. Santos-Riviera,* 183 F.3d 367, 369 (5th Cir. 1999); *see also United States v. Boren,* 278 F.3d 911, 913 (9th Cir. 2002) (stating that the Ninth Circuit reviews a district court's dismissal of an indictment based on its interpretation of a federal statute *de novo*).

III. DISCUSSION

A. Previous Treatment of § 355(i)

The Ninth Circuit, Eighth Circuit, and district court each used different legal frameworks to analyze the question of whether § 355(i) allows the FDA to criminalize conduct of clinical investigators who fail to adhere to the FDA's regulations regarding record-keeping and reporting requirements.

1. Ninth Circuit's Smith *Opinion*

The Ninth Circuit based its analysis on prior circuit caselaw which states that "[e]xecutive agencies have the authority to establish regulations which are enforced by criminal penalties only when Congress has provided 'sufficient guidelines and standards for the exercise of the authority.'" *Smith,* 740 F.2d at 738 (citation omitted). The court found that the statute placed the burden for record-keeping and reporting requirements on only manufacturers and sponsors. The court stated that the general authorization language contained in the statute to be "insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability." *Id.* at 738. Ultimately, the court found § 355(i) to be ambiguous as applied to clinical investigators, invoked the rule of lenity,[2] and affirmed the

---

[2] "The rule of lenity provides that 'when a choice must be made between two readings of what conduct Congress has made a crime, it is appropriate, before choosing the harsher alternative,

(Continued on following page)

district court's dismissal of the indictment against the defendant-clinical investigator.

2. *Eighth Circuit's* Garfinkel *Opinion*

The Eighth Circuit first determined that whether § 355(i) provides sufficient guidance for the issuance of clinical investigator regulations that resulted in criminal penalties presented a (1) statutory issue related to whether § 355(i) authorized the FDA regulations at issue and a (2) constitutional issue related to the nondelegation doctrine. *Garfinkel,* 29 F.3d at 453-54. The *Garfinkel* court began its analysis of § 355(i) by interpreting the Ninth Circuit's decision in *Smith,* and determined that, while not explicitly mentioned, the *Smith* decision was premised on the Ninth Circuit's determination that § 355(i) violated the nondelegation doctrine. *Id.* at 454. The Eighth Circuit also noted that the *Smith* court's initial basis for dismissing the indictment was "that § 355(i) lacked *sufficient standards* for [the] FDA to promulgate regulations imposing criminal penalties upon clinical investigators." *Id.*

The Eighth Circuit then analyzed § 355(i) and held the language of the statute to be ambiguous as it related to the FDA's authority over clinical investigators. *Id.* at 456. The court engaged in a *Chevron*

---

to require that Congress should have spoken in language that is clear and definite.'" *United States v. Orellana,* 405 F.3d 360, 370 (5th Cir. 2005) (citation omitted).

doctrine analysis to determine whether the "FDA's interpretation of § 355(i) 'reflect[ed] a plausible construction of the plain language of the statute and does not otherwise conflict with Congress'[s] expressed intent.'" *Id.* (citation omitted). *See also Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).[3] The *Garfinkel* court reviewed § 355(i)'s legislative history and held that § 355(i) authorized the promulgation of clinical investigator record-keeping regulations. *Garfinkel*, 29 F.3d at 457.

The Eighth Circuit then analyzed § 355(i) under the constitutional issues presented by the nondelegation doctrine. *Id.* The court examined the language of § 355(i); the purpose of the Food, Drug, and Cosmetic Act, along with its factual background; and the statutory context of the Act's standards. *Id.* at 458. Ultimately, the court disagreed with what it characterized as the Ninth Circuit's determination that the statute violated the nondelegation doctrine, and held that "the standards enunciated by the Act, along with judicial review and the procedural requirements dictated by the [Administrative Procedure Act], impose[d] sufficient restraints upon FDA to satisfy the

---

[3] Courts apply an analysis of the *Chevron* doctrine when a party challenges an administrative agency's authority to construe a statute, specifically the agency's authority to interpret the statute and promulgate regulations in accordance with that interpretation. *See generally Chevron*, 467 U.S. at 837.

constitutional concerns underlying the nondelegation doctrine." *Id.* at 459.

3. District Court's Analysis

The district court examined § 355(i) and concluded that it does not authorize criminal penalties for violations by clinical investigators in maintaining adequate and accurate records. In making this determination, the district court first examined the nondelegation doctrine and the Supreme Court's decision in *Touby v. United States,* 500 U.S. 160, 165 (1991).

In *Touby,* the Supreme Court stated that "Congress may not constitutionally delegate its legislative power to another branch of Government," but Congress does not violate the Constitution as long as it provides "an *intelligible principle* to which the person or body authorized to [act] is directed to conform." *Id.* (emphasis added). The district court noted, however, that *Touby* did not resolve the issue as to whether more specific guidance is required "when Congress authorizes another Branch to promulgate regulations that contemplate criminal sanctions . . . [and that] pose a heightened risk to individual liberty." *Id.* The district court concluded that in *Touby,* the Attorney General was permitted to promulgate regulations resulting in criminal sanctions because the relevant statute included six specific factors that the Attorney General must consider in making its determination regarding criminal sanctions.

The district court then examined *Smith* and *Garfinkel* and agreed with the reasoning in *Smith*. The district court concluded that the language of § 355(i) does not provide sufficient guidelines to the FDA regarding clinical investigators to satisfy *Touby*'s intelligible principle requirement. The district court correctly noted that the newer, more explicit FDA regulations imposing responsibility on clinical investigators to maintain adequate and accurate records are not dispositive on the issue of whether the actual statutory language survives the constitutional inquiry.[4] The district court, therefore, focused solely on the language of § 355(i) and concluded that Congress did not specifically authorize regulations giving rise to criminal liability under § 355(i), and dismissed counts forty-one through fifty-five of the superseding indictment.

---

[4] While not directly referenced by the district court, it is important to note that the Eighth Circuit relied in part on changed regulations that are not dispositive of the nondelegation doctrine issues in this case. In *Whitman v. American Trucking Associations, Inc.*, the Supreme Court explained that in a delegation challenge "the constitutional question is whether the statute has delegated legislative power to the agency." 531 U.S. 457, 472 (2001). An agency cannot cure "an unconstitutionally standardless delegation of power by declining to exercise some of that power." Therefore, the change in the FDA's regulations to more specific language dealing with clinical investigators, after the *Smith* decision and before the *Garfinkel* decision, is not dispositive of the issue of whether § 355(i) provides a constitutional delegation of authority to the FDA to promulgate regulations criminalizing conduct of clinical investigators for failing to maintain proper record-keeping and reporting requirements.

B. Proper Legal Framework

Dr. Palazzo concedes that the FDA has authority to impose record-keeping requirements on clinical investigators through regulations and properly did so through 21 C.F.R. § 312.62. If the parties questioned whether § 355(i) provided *sufficient guidance* for the FDA to promulgate regulations requiring clinical investigators to adhere to certain record-keeping requirements, the nondelegation doctrine would be an issue in this case. *See, e.g., Garfinkel,* 29 F.3d at 453-54. Similarly, if the parties disputed whether § 355(i) *authorized* the FDA regulations at issue in this case, this Court would need to engage in a *Chevron* analysis to assess § 355(i)'s statutory construction. *See, e.g., Id.*

The sole issue on appeal in the instant case, however, is whether 21 U.S.C. §§ 351(e) and 355(i) allow the imposition of criminal penalties on clinical investigators who violate the record-keeping requirements found in 21 C.F.R. § 312.62. This issue involves the scope of § 355(i), not the FDA's authority to promulgate regulations, and we must merely "ascertain[ ] the scope of [§ 355(i)], which in turn requires us to construe the statute." *See United States v. Kay,* 359 F.3d 738, 740 (5th Cir. 2004). Thus, the issue on appeal requires this court to engage only in statutory interpretation.

"The starting point for interpreting a statute is the language of the statute itself." *Id.* at 742. (quotation omitted). We follow the "plain and unambiguous

meaning of the statutory language." *Id.* (quotation omitted). "If the statute is ambiguous, we may look to the legislative history or agency interpretations for guidance." *United States v. Orellana,* 405 F.3d 360, 365 (5th Cir. 2005) (citation omitted).

C. Analysis

Dr. Palazzo argues that § 355(i) only provides criminal sanctions for manufacturers and sponsors of clinical investigational studies. Therefore, she concludes that she cannot be held criminally liable for violating §§ 331(e) and 355(i) because she is not a manufacturer or sponsor of an investigational study. Dr. Palazzo maintains that the only permissible or lawful penalty for failure to adhere to these record-keeping requirements is disqualification from other investigational studies, a stated penalty within the FDA regulations. *See* 21 C.F.R. § 312.70. In addition, Dr. Palazzo argues that § 355(i) only gives the Secretary the authority to grant exemptions from criminal liability, not the authority to impose criminal liability on clinical investigators who violate the FDA's properly promulgated regulations.

The Government asserts that the FDA regulations fill in the details of the criminal statute. The Government notes that Congress may broadly assign authority to the Executive Branch. In this instance, the Government argues that the plain language of § 355(i) and its legislative history demonstrate that Congress authorized the FDA to promulgate criminally

enforceable record-keeping regulations that apply to clinical investigators.

1. The Scope of Section 355(i)

Section 355(i) states:

> (i) Exemptions of drugs for research; **discretionary and mandatory conditions**; direct reports to Secretary.
>
> (1) The Secretary **shall** promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. **Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon –**
>
> . . . .
>
> (C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the

filing of an application pursuant to subsection (b); and

. . . .

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. **Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.**

21 U.S.C. 355(i) (emphasis added).

Based on the text of the statute, it is clear that § 355(i) addresses three separate issues regarding clinical drug testing. First, § 355(i) explicitly requires the Secretary of the FDA to promulgate regulations providing exemptions of drugs for research from earlier subsections contained in 21 U.S.C. § 355, which regulate "New Drugs." Second, § 355(i) allows the Secretary, in his/her discretion, to issue regulations

regarding those exemptions in an effort to "protect[] the public health." Section 355(i) provides a non-exhaustive list of conditions upon which the Secretary may provide exemptions. Third, § 355(i) provides requirements for sponsors and manufacturers to make direct reports to the Secretary and explicitly states that clinical investigators are not required to submit reports directly to the Secretary.

On its face, § 355(i) does not provide criminal liability for sponsors and manufacturers of investigational drug studies or clinical investigators. Violations of § 355(i) are prohibited in 21 U.S.C. § 331(e), and criminal penalties for violating § 331(e) are found in 21 U.S.C. § 333(a). In addition, § 355(i) does not contain an explicit requirement governing the conduct of clinical investigators. The record-keeping and reporting requirements applicable to clinical investigators are contained in the regulations promulgated by the FDA in accordance with the authority given the FDA by Congress. Thus, we must turn to §§ 331(e) and 333 and the FDA's regulations concerning clinical investigators to determine whether clinical investigators are subject to criminal liability for failing to adhere to certain record-keeping and reporting requirements.

2. FDA Regulations and 21 U.S.C. §§ 331(e) and 333

The FDA regulations at issue in this case fall squarely within the second statutory category: the

Secretary's ability to promulgate regulations to protect the public health. Accordingly, the Secretary promulgated extensive regulations governing the conduct of clinical investigators.

We first look to the specific section of the regulations which Dr. Palazzo is charged with violating, 21 C.F.R. § 312.62(b). 21 C.F.R. § 312.62 is entitled "[i]nvestigator record[-]keeping and record retention." Section 312.62(b) provides requirements for clinical investigators, like Dr. Palazzo, "to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug." We must now consider how this properly promulgated regulation fits within the statutory context of the FDA, specifically §§ 355(i), 331(e) and 333.

21 U.S.C. § 331 sets out certain prohibited acts under the Food, Drug, and Cosmetics Act, and § 331(e) prohibits a failure to establish or maintain *any* record, or make *any* report, required under § 355(i), but § 331(e) does not limit its prohibition only to reports required to be made directly to the Secretary. Section 355(i) allows the Secretary to establish reporting requirements, and the Secretary promulgated regulations specific to investigators in 21 C.F.R § 312.62(b). These are properly considered to be "required" reporting and record-keeping requirements under § 331(e), as § 355(i) allows the Secretary discretionary authority to issue regulations in an effort to protect the public health. The penalties for

violating § 331(e) are found in 21 U.S.C. § 333, and specifically state that those violating § 331(e) "shall be imprisoned for not more than one year or fined not more than $1,000, or both." 21 U.S.C. § 333(a)(1).

As stated previously, Dr. Palazzo conceded that § 355(i) provides the FDA with unambiguous authority to promulgate regulations requiring clinical investigators to adhere to specific record-keeping and reporting requirements. Dr. Palazzo, therefore, was required under § 355(i), via 21 C.F.R. 312.62(b), to adhere to the FDA's record-keeping and reporting requirements. Section 331(e) delineates what acts are prohibited, and specifically prohibits a failure to establish or maintain any record or make any report as required under § 355(i). Nowhere in § 331(e) does the statute indicate that it only serves to prohibit a failure to establish or maintain records and reports submitted directly to the Secretary of the FDA. Furthermore, the Government correctly notes that Dr. Palazzo points to no ambiguous language in § 331(e) that would cause her to be unclear about whether she could be prosecuted for violating the FDA's record-keeping requirements established by § 312.62(b). Thus, reviewing § 312.62(b) in conjunction with §§ 355(i), 331(e), and 333(a)(1) makes it apparent that the scope of the statute allows clinical investigators to be subjected to criminal liability.

IV. CONCLUSION

For the foregoing reasons, the district court's dismissal of counts forty-one through fifty-five is REVERSED and REMANDED to the district court for further proceedings consistent with this opinion.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA	**CRIMINAL ACTION**
VERSUS	**NO: 05-0266**
MARIA CARMEN PALAZZO, M.D., PH.D., MMM	**SECTION: "S"**
	(Filed Oct. 24, 2007)

ORDER AND REASONS

IT IS HEREBY ORDERED that Maria Carmen Palazzo's motion to suppress is **DENIED**. (Document #38.)

IT IS FURTHER ORDERED that Palazzo's motion to dismiss counts 41-55 of the superseding indictment (counts 3-17 of the original indictment) is **GRANTED**. (Document #31.)

IT IS FURTHER ORDERED that Palazzo's motion to sever counts 41-55 of the superseding indictment (counts 3-17 of the original indictment) is **DENIED AS MOOT**. (Document #34.)

IT IS FURTHER ORDERED that Palazzo's motion to dismiss counts 1-27 of the superseding indictment (count 1 of the original indictment) for failure to state an offense and, alternatively, for a bill of particulars is **DENIED**. (Document #80.)

IT IS FURTHER ORDERED that Palazzo's motions to dismiss counts 28-40 of the superseding

indictment (count 2 of the original indictment) is **DENIED**. (Document #29.)

IT IS FURTHER ORDERED that the motion to strike surplusage is **DENIED**. (Document #33.)

IT IS FURTHER ORDERED that, because of the filing of the superseding indictment, the motion to dismiss counts one and two of the original indictment as duplicitous is **DENIED AS MOOT**. (Document #30.)

I. BACKGROUND

Maria Carmen Palazzo, M.D., Ph.D., MMM[1] (Dr. Palazzo), a licensed medical doctor specializing in psychiatry, was a Medicare provider authorized to submit bills for reimbursement for certain medical services to eligible Medicare beneficiaries. Medicare is funded with Social Security taxes and is administered by the United States Department of Health and Human Services (HHS) through the Centers for Medicare and Medicaid Services (CMS), an agency of HHS.

Mutual of Omaha received, settled, and paid Medicare Part A claims for Touro Infirmary, pursuant to a contract with CMS. Arkansas Blue Cross and Blue Shield paid Medicare Part B claims submitted

---

[1] In addition to her medical degree, Dr. Palazzo holds a Ph.D in philosophy and a Master's Degree in Medical Management.

by Medicare beneficiaries or Louisiana health care providers, pursuant to a contract with CMS. Dr. Palazzo submitted Medicare Part B bills to Blue Cross/Blue Shield using a HCFA/CMS form 1500, the standard claim form in the health insurance industry.

On July 5, 2000 and July 27, 2001, Dr. Palazzo entered into a professional services agreement with Touro, under which Dr. Palazzo would provide consultation services for the Adult Psychiatric Programs at Touro. On June 1, 2002 and June 1, 2003, Dr. Palazzo and Touro entered an agreement for Dr. Palazzo to provide medical director services for the Inpatient Adult Psychiatric and Adult Partial Hospitalization Programs (PHPs) at Touro.[2] Each agreement was for a one-year term and provided compensation at a rate of $150 per hour up to $144,000 per year. Dr. Palazzo was required to provide a written monthly statement documenting the amount of time spent and detailing services she rendered.

On October 31, 2000, SmithKline Beecham, Corporation (SKB) hired Dr. Palazzo as a clinical investigator to carry out clinical studies to evaluate the efficacy and safety of Paxil in children and adolescents with obsessive-compulsive disorder. Dr. Palazzo

---

[2] PHPs provide intensive psychiatric care and closely resemble that of a highly structured, short term, inpatient hospital program. Continued treatment requires evidence that less intensive treatment options could not provide the level of support necessary to maintain the patient and to avoid hospitalization.

agreed, *inter alia,* to personally review all case report forms regarding each study subject and received $5,410 for each subject who completed the study. On February 9, 2001, SKB entered into a contract with Dr. Palazzo to participate as a clinical investigator to assess the long term safety of Paxil in children and adolescents with major depressive disorder or obsessive-compulsive disorder. Dr. Palazzo agreed to comply strictly with the study protocol and to review personally all information regarding the study subject. SKB agreed to pay Dr. Palazzo $5,020 for each study subject who completed the study. When Dr. Palazzo did not comply with the criteria to provide satisfactory research records, her contract to participate in the drug studies was terminated.

On August 25, 2005, the grand jury charged Dr. Palazzo with two counts of health care fraud and 15 counts of failure to maintain records of the clinical drug studies in violation of 21 U.S.C. § 355(i). On January 14, 2007, the grand jury returned a superseding indictment charging Dr. Palazzo with 40 counts of health care fraud and 15 counts of violations of § 355(i).

The allegations of health care fraud in the superseding indictment are as follows. From a date unknown until December 31, 2003, Dr. Palazzo fraudulently obtained money from Medicare by billing for comprehensive subsequent hospital visits to patients once a week, when in fact she did not conduct individual face-to-face visits requiring complex medical decision making. Dr. Palazzo instead summoned PHP

employees to her 7th floor office to create patient notes to facilitate a Medicare billing after all of the PHP patients left the facility for the day.

Further, from August 2000 until May 2002, Dr. Palazzo used a physician's assistant to create false documents supporting the appearance of daily medical visits to PHP patients to receive money to which she was not entitled. Dr. Palazzo routinely signed false CMS Form 1500's that did not identify that the physician's assistant was the provider of the service for which she was billing Medicare and Medicaid, but falsely represented that she had personally performed the services. Dr. Palazzo received approximately $477,901 from Medicare and $175,651 from Medicaid.

The superseding indictment further alleges that, as part of the scheme to defraud, Dr. Palazzo did not allot adequate time for physician assistant visits; instructed the physician assistant to be creative in composing patient notes without providing beneficial services; greeted patients personally for the sole purpose of billing; submitted bills for face-to-face visits when group therapy was provided; falsely identified herself as the provider of services in order to receive 100% of the fee schedule reimbursement; submitted bills for face-to-face services when she participated in non-reimbursable team medical conferences; placed patients in group homes over which she had ownership or control; required "Touro at Home," Touro's home health agency, to hire two nurses who had provided services to the defendant's patients for years; kept long-term patients enrolled in the PHP for

periods far exceeding what was medically necessary without significant changes in the plans of care; and discharged almost all of her patients from the Touro PHP when she was no longer medical director, when she had previously certified their ongoing need for PHP care for years.

On November 4, 2004, the government executed search warrants and seized evidence at Dr. Palazzo's home and office. Dr. Palazzo filed a motion to suppress the seized evidence. Moreover, Dr. Palazzo filed a motion to suppress count two of the indictment, a motion to dismiss counts one and two as duplicitous, a motion to dismiss counts three through seventeen of the original indictment, a motion to dismiss counts one through twenty-seven, a motion to strike surplusage, and a motion to sever. The government filed a motion *in limine*.

II. DISCUSSION

A. Motion to suppress seized evidence

Dr. Palazzo contends that the search warrants executed at her home at [Home Address Omitted] and at her office on the 7th floor of 3450 Chestnut Street on November 4, 2004, are invalid, and the evidence seized pursuant to the warrants must be suppressed. Specifically, Dr. Palazzo argues that the affidavits in support of two warrants failed to establish probable cause to seize records of Creative Investment (a real estate venture), GGS Psychiatric Clinic of New Orleans, LLC (the doctor's drug research company),

Palazcoe, LLC (the doctor's real estate investment company), or Decisioncare, Inc. (psychiatric utilization review consultants); the affidavits contain unsupported, conclusory allegations by the affiant; the allegations are attributed to employees and former employees without any indicia of reliability; the government did not review the Form 1500s in preparing the affidavits accusing Dr. Palazzo of submitting fraudulent bills; the government did not inform the magistrate judge that some of the services billed to Medicare and Medicaid may have been performed by Dr. Palazzo's staff of physician's assistants, psychologists, and social workers and billed under Dr. Palazzo's name and provider number as "incident to" services; the affidavits failed to establish probable cause that the drug study records would be found in either of the locations to be searched because the Food and Drug Administration's (FDA) inspection of the records concluded on August 28, 2001; and the affidavits are deficient because they are overly broad ("travel records, credit card records, property records, gambling records, ownership and upkeep of a race horse"). Dr. Palazzo argues that, as a result, the magistrate judge was misled into thinking that Dr. Palazzo submitted fraudulent bills, claiming to have worked more than 24 hours on certain days, and that the informants' statements were credible.

The government argues that specificity in a warrant is not necessary, and a description is sufficiently particular when it enables a searcher to reasonably ascertain and identify the items to be seized. The

government argues that the affidavit clearly established that the health care fraud was contingent on the amount of hours spent providing treatment in a day. Any activity associated with Dr. Palazzo's professional whereabouts, social activities, and other business ventures would disable her from the ability to practice medicine to the extent of which she billed Medicare and Medicaid. The government argues that it is of no consequence that the names of the entities in question were not mentioned in the affidavit because the investigators had the authority to seize any items that could be reasonably used to determine Palazzo's whereabouts during the 24 hour periods for which she was billing for services she allegedly provided.

"A valid search warrant may be issued only upon a finding of probable cause." *United States v. Perez*, 484 F.3d 735, 740 (5th Cir. 2007). "The information necessary to show probable cause must be contained within a written affidavit given under oath." *Id.* "Probable cause does not require proof beyond a reasonable doubt; a magistrate need only have a substantial basis for including that a search would uncover evidence of wrongdoing." *Id.* "A magistrate's determination is entitled to deference by reviewing courts." *Id.* "[I]tems of an 'incriminatory character' which are found in the course of a legal search, yet which were not described in the search warrant, may be seized." *United States v. Loe*, 248 F.3d 449, 460 (5th Cir. 2001). "Absent evidence of an intentional material misrepresentation or omission in the affidavit, the

warrant will not be invalidated." *United States v. McCarty,* 36 F.3d 1349, 1356 (5th Cir. 1994).

A search warrant was obtained for documents and records "relating to Medicare Parts A and B, Louisiana Medicaid billings, and Food and Drug Administration (FDA) records for patient care purportedly provided by Dr. Maria Carmen Palazzo" supported by the affidavit of Juliana Etland, a Special Agent with the HHS, Office of Inspector General. Rec. doc. 63, exh. 15. The affidavit was based on "direct personal knowledge derived from investigation and information provided by person[s] believed to be credible and to possess accurate information regarding Dr. Palazzo." The persons referred to in the affidavit were past employees, current associates of Dr. Palazzo, and FDA investigators. The affidavit is specific as to the findings of the investigators, who reviewed records and conducted interviews at the various locations where Dr. Palazzo practiced, concerning violations of the Medicare program, the Medicaid program, and FDA regulations. The gravamen of the accusations was that Dr. Palazzo billed for more hours of service than were actually rendered. A compilation of 112 days of billing records was made in order to illustrate the excessive number of hours per day for which Dr. Palazzo billed federal and state insurance programs. The affidavit is specific as to the location of documents and records, such as filing cabinets containing patient records, patient sign-in sheets and notes, appointment books, financial records, billing records, and stored business records.

Further, the government sought to seize Dr. Palazzo's computer data and hardware to gather physical evidence of Medicare, Medicaid, and FDA fraud based on a belief that the computer system was used in the practice and that it contained evidence of fraud. The extent of the items seized was based on consultation with an FBI special agent, who had expertise in retrieving and analyzing electronically stored data.

The court finds that the affidavit sufficiently referred to specific items to be seized and set out the reasons for the search of the particular items. *See United States v. Shugart,* 117 F.3d 838, 845 (5th Cir 1997) ("The incorporation of the detailed statement satisfied the particularity requirement.). The affidavit establishes, by a fair probability, that the search would produce health care records, drug study records, and evidence of how much time Dr. Palazzo spent in non-patient activity. Palazzo points to no material misrepresentation that would invalidate the warrant.

Therefore, the warrant for the search was supported by probable cause, and the motion to suppress the seized evidence is denied.[3]

---

[3] Because the court denies the motion to suppress the seized evidence, an evidentiary hearing pursuant to *Franks v. Delaware* is not necessary.

B. Motion to dismiss counts 41-55 of the superseding indictment

Palazzo moves to dismiss counts 41-55 of the superseding indictment (counts 3-17 of the original indictment). In counts 41-55, the grand jury charges that Palazzo failed to prepare and maintain records required under 21 U.S.C. § 355(i)[4] and 21 C.F.R.

---

[4] 21 U.S.C. § 355(i) provides in relevant part.

> (i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary
>
> (1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon –
>
> . . . .
>
> (C) the establishment and maintenance of such records, and the making of such reports to the Secretary, **by the manufacturer or the sponsor of the investigation of such drug**, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section.

Section 331(e) imposes criminal penalties for failure to establish or maintain records as required under § 355(i).

§ 312.62(b),[5] *i.e.* adequate and accurate case histories on each individual administered the investigational drug, Paxil, or employed as a control in the investigation. Palazzo contends that § 355(i) allows the Secretary of the HHS to impose record-keeping requirements on the manufacturer or the sponsor of the investigation, but does not authorize the imposition of criminal liability upon the clinical investigator for failing to maintain accurate records. She argues that, although she was subject to FDA regulations, she was not exposed to criminal liability related to maintaining records for the study.

"The Constitution provides that '[a]ll legislative Powers herein granted shall be vested in a Congress of the United States.'" *Touby v. United States,* 111 S.Ct. 1752, 1755 (1991) (quoting U.S. Const., Art. I,

---

[5] Section 312.62(b) provides:

Investigator recordkeeping and record retention.

(b) Case histories. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

§ 1.). "From this language the Court has derived the nondelegation doctrine: that Congress may not constitutionally delegate its legislative power to another branch of Government." *Id.* "The nondelegation doctrine is rooted in the principle of separation of powers that underlies our tripartite system of Government." *Id.* at 1755-56. "Congress does not violate the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors." *Id.* at 1756. "So long as Congress lay[s] down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power." *Id.* (internal quotation and citation omitted).

In *Touby,* the Supreme Court did not resolve the issue as to whether more specific guidance is required "when Congress authorizes another Branch to promulgate regulations that contemplate criminal sanctions . . . [that] pose a heightened risk to individual liberty." *Id.* However, *Touby* is instructive because it demonstrates conditions under which the delegation of power satisfies constitutional concerns. *Touby* examined an expedited procedure by which the Attorney General can schedule a substance in schedule I on a temporary basis under 21 U.S.C. § 811(h), when doing so is necessary to avoid an imminent hazard to the public safety. *Id.* at 1756. The Attorney General determined that temporary scheduling was necessary to enable the government to respond to the threat posed by dangerous, new "designer drugs." *Id.* The

Supreme Court held that Congress' authorization to promulgate regulations "passes muster" in this case because the Attorney General's discretion to define criminal conduct was meaningfully constrained inasmuch as the statute includes six factors that the Attorney General must consider and a 30-day notice requirement. *Id.* Moreover, 21 U.S.C. 812(b) identifies mandatory requirements that must be satisfied. *Id.* at 1757. The Supreme Court stated that the multiple, specific restrictions on the Attorney General's discretion to define criminal conduct "satisfy the constitutional requirements of the nondelegation doctrine." *Id.*

The Court of Appeals for the Ninth Circuit and the Eighth Circuit have addressed the nondelegation doctrine as it applies to § 355(i) and reached different conclusions. In *United States v. Smith,* 740 F.2d 734 (9th Cir. 1984), the Court of Appeals considered whether § 355(i) in conjunction with 21 C.F.R. 312.1 "make it a crime for a clinical investigator to maintain inadequate or inaccurate records." The district court had dismissed the counts under § 355(i) because the statute and regulations did not attach criminal liability to clinical investigators, and the Court of Appeals affirmed the decision. *Id.* at 736-37. The Court of Appeals reasoned as follows:

> Although the statute expressly authorizes regulations which impose affirmative duties on manufacturers and the sponsors of clinical investigations, we are reluctant to read the statute as authorizing criminal

penalties for the violation of any regulation promulgated pursuant to the statute's *general* authorizing language. In creating the obligation to maintain drug testing records, Congress expressly imposed the burden on manufacturers and sponsors. § 355(i)(3). The government asks that we extend the statutory obligation to include clinical investigators pursuant to the statute's general regulatory authority which allows the Secretary to establish "other conditions relating to the protection of public health" before exempting manufacturers from the statute's basic drug approval application requirements. § 355(i). Such general authorizing language, however, is *insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability.* Executive agencies have the authority to establish regulations which are enforced by criminal penalties only when Congress has provided "sufficient guidelines and standards for the exercise of the authority." *United States v. Davis,* 564 F.2d 840, 844 (9th Cir. 1977). (Emphasis supplied.)

Moreover, even if Congress had provided standards for extending the record keeping requirement to investigators by regulation, the regulatory language falls short of imposing an explicit affirmative duty on the investigators to maintain accurate records. . . . Absent such a clear articulation of duty, we are not prepared to fasten criminal liability

> to the investigator who fails to fulfill his or her obligation to the sponsor.
>
> . . . .
>
> The statute and regulations at issue here do not impose a clear duty on investigators to maintain accurate records. They only impose affirmative duties on drug manufacturers and the sponsors of clinical investigations. If the FDA discovers that an investigator has falsified information in forms submitted to the sponsor, the FDA, pursuant to the regulations, may conduct an administrative hearing and revoke the investigator's entitlement to work with investigational drugs. 21 C.F.R. § 312.1(c).[6]

The United States Court of Appeals for the Eighth Circuit disagreed with *Smith* in *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994). Even though the regulations in *Smith* had been amended since *Smith* was decided, the district court adopted *Smith* and dismissed counts charged against a clinical investigator under § 355(i) because the statute does not contain language authorizing the FDA to promulgate regulations covering protocol investigators. *Id.* at 453. The Court of Appeals reversed and remanded, holding that § 355(i) "authorizes the investigator record keeping regulations at issue here and this delegation of

---

[6] Section 312.1(c) was in force when *Smith* was decided. The regulation was amended in 1987 to address recordkeeping by investigators. *See* § 312.62.

authority to FDA satisfies the constitutional concerns of the nondelegation doctrine." *Id.* at 459. Applying *Touby,* the Court of Appeals examined the language of § 355(i), the purpose of the Act, and the statutory context of the standards and concluded that § 355(i) imposes significant guidelines upon the FDA which "more than satisfy the requirement that Congress lay down an intelligible principle to restrain the agency's authority." *Id.* at 458.

The Court of Appeals also held that "the language of the statute is ambiguous at least as it relates to FDA's authority over clinical investigators,"[7] and examined the "legislative history to determine whether FDA's interpretation conflicts with Congress' expressed intent." *Id.* at 456. The Court of Appeals agreed that "Congress' focus was on the manufacturers and sponsors of investigational drugs" but found "nothing in the legislative history to indicate that Congress intended to limit FDA's authority to the sponsors and manufacturers." *Id.*

The court agrees with the reasoning of the Ninth Circuit in *Smith* that § 355(i) does not authorize

---

[7] Although *Garfinkel* states that the statute is ambiguous as to the delegation of authority, the case does not address the rule of lenity. The rule of lenity "dictates that ambiguous statutory language in criminal statutes should be strictly construed to ensure that we do not penalize conduct that Congress did not intend to criminalize." *United States v. Cuellar,* 478 F.3d 232, 300 (5th Cir. 2007). "The rule of lenity is triggered if the interpretive issue is subject to some doubt, and the doubt must be resolved in favor of the defendant." *Id.*

criminal penalties for violations by clinical investigators in maintaining adequate and accurate records. Congress did not grant broad authority, but specifically singled out manufacturers and sponsors, not clinical investigators. Unlike the decision in *Garfinkel,* the court concludes that nothing in the language of § 355(i) provides sufficient guidelines regarding clinical investigators to serve as an intelligible principle to which the HHS or the FDA is directed to conform. The statute falls short of the multiple restrictions or mandatory requirements of *Touby* with regard to any party other than the manufacturer or the sponsor of the investigation. Although the amended, post-*Smith* regulations impose responsibility on clinical investigators to maintain adequate and accurate records, the focus of the constitutional inquiry is not directed to the amended regulations, but to the language of § 355(i) and whether the statute is specific as to the restraints on imposing criminal conduct. Accordingly, the court concludes that Congress did not specifically authorize regulations giving rise to criminal liability under § 355(i), and the motion to dismiss counts 41-55 of the superseding indictment is granted.

C. Motions to dismiss for failure to state an offense

Dr. Palazzo contends that the superseding indictment fails to allege an offense under the health care fraud statute. "The Federal Rules of Criminal Procedure require that the indictment be 'a plain, concise

and definite written statement of the essential facts constituting the offense charged.'" *United States v. Ratcliff*, 488 F.3d 639, 643 (5th Cir. 2007); Fed. R. Civ. Pro. 7(c)(1). "The indictment is sufficient if it alleges every element of the crime charged and in such a way as to enable the accused to prepare his defense and to allow the accused to invoke the double jeopardy clause in any subsequent proceeding." *Id.* (internal quotation and citation omitted). The law does not compel a ritual of words, and the indictment's validity depends on practical, not technical considerations. *Id.*

The health care fraud statute, 18 U.S.C. § 1347, under which Dr. Palazzo is charged provides:

> Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice –
>
> (1) to defraud any health care benefit program; or
>
> (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program,
>
> in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. If the violation results in serious bodily injury . . . such person shall be fined under this title or imprisoned not more than 20 years, or both; and if the violation results in death, such

person shall be fined under this title, or imprisoned for any term of years or for life, or both.

1. Motion to dismiss counts 1-14 and 15-27 of the superseding indictment[8] (count 1)

Dr. Palazzo contends that the superseding indictment fails to allege in counts 1-14 fraud in Medicare billing for the PHP program because the necessary Evaluation and Management (E&M) Key Components were not alleged. Dr. Palazzo further contends that counts 15-27 fail to allege that she submitted false bills to Medicare and Medicaid as the provider of services that a physician's assistant actually performed because there are no allegations that the E&M Key Components were not accomplished. Alternatively, Dr. Palazzo requests a bill of particulars specifying the "face to face" treatments that Dr. Palazzo allegedly billed for in counts 1-14 and the specific activities of the physician assistants that form the basis of counts 15-27.

The American Medical Association (AMA) assigns five-digit numerical codes to medical procedures performed by health care providers (Current Procedural

---

[8] Counts 1-14 allege fraudulent billing for CPT codes 99232 and 99233. Counts 15-27 allege that Dr. Palazzo submitted false bills to Medicare and Medicaid for services performed by a physician's assistant.

Terminology or CPT codes). Medicare, Medicaid, and insurance companies establish a fee for each service rendered, as described by its CPT code. CPT code books contain several codes for professional services classified as E&M services. E&M CPT codes are divided into broad categories such as office visits, hospital visits, and consultations, and two or more sub-categories of E&M services. The subcategories are divided into levels that describe the nature of physician's work by type and place of service and the patient status, including the complexity of the service and the time typically required to provide the service. Fees paid are commensurate with the amount of work required.

Codes 99231, 99232, and 99233 are hospital care codes for reviews of medical records and results of diagnostic studies and changes in admitted patients. These are services that require the physician to meet face-to-face with a patient. A physician typically requires 15, 25, and 35 minutes at the bedside and on the patient's hospital floor or unit to perform the necessary medical services, such as obtaining a comprehensive history or conducting a physical exam of the patient. Code 99361 is a team medical conference with an interdisciplinary team of health professionals to coordinate activities of patient care. The expected time is 30 minutes, but Medicare provides no reimbursement for this service.

A physician's assistant is a practitioner permitted by the State to provide medical services under the supervision of a physician. Medicare reimburses

physician's assistant services at 85% of the scheduled fee for the same service if provided by a physician. Payment is made to the employer, not directly to the physician's assistant.

The superseding indictment in counts 1 to 27 alleges a scheme to defraud health care benefit programs by billing for services that were not provided by Dr. Palazzo, creating false documentation to collect payment for benefits and services not provided, and using physician assistants to see the patients and create false documentation to support false bills to Medicare and Medicaid. Each of the codes upon which the billing is based require that Dr. Palazzo spend some time with the patient and have components describing the complexity of the visits under each code. Accordingly, the superseding indictment states the essential facts constituting the offense charged. The motion to dismiss counts 1-27 of the superseding indictment is denied.

Dr. Palazzo requests a bill of particulars to inform her of the specific charges against her. The purpose of a bill of particulars is to inform the accused of the charge with sufficient precision to reduce trial surprise, to enable adequate defense preparation, and critically, by the fleshing out of the charges to illuminate the dimensions of jeopardy." *United States v. Davis*, 582 F.2d 947, 951 (5th Cir.1978). However, the discovery device should not used to compel detailed disclosure of the government's evidence before trial. *United States v. Sheriff*, 546 F.2d 604, 606 (5th Cir.1977).

The request for a bill of particulars is denied. Counts 1-14 of the superseding indictment identify the billing alleged to be fraudulent by patient, date, claim number, and CPT code, based on Dr. Palazzo's failure to see those patients face-to-face. Counts 15-27 identify the date, patient, and claim number. Counts 28-40 identify the dates of submission of false invoices to Touro to support claims for reimbursement from Medicare.

2. Motion to dismiss counts 28-40 of the superseding indictment

Dr. Palazzo contends that counts 28-40 fail to state an offense for defrauding a health care benefit program. She argues that the superseding indictment alleges that she obtained money from Touro Infirmary by falsely submitting invoices, but charges Dr. Palazzo with defrauding Medicare by obtaining money owned by and under the custody and control of Medicare. Dr. Palazzo argues that there are no allegations in counts 28-40 that she made any representations to Medicare, received any money from Medicare, or had any contact with Medicare. Dr. Palazzo contends that she submitted her invoices to Touro, Touro paid her for her services as a Medical Director, and Medicare partially reimbursed Touro for the money it paid Dr. Palazzo.

The court finds that the charges in counts 28-40 of the superseding indictment adequately state an accusation of an offense that Dr. Palazzo executed a

scheme to defraud Medicare. The superseding indictment alleges that a "health care benefit program" was the victim of the fraud, which was accomplished by making false representations to Touro on specific invoices in order to obtain money under the custody and control of Medicare. The charges reflect the terms of each "Professional Services Agreement" with Touro, *e.g.* gov't's exh. 2, which contemplate that payment for services will be made by Medicare or another health care benefit program. The agreement requires that Dr. Palazzo "assist the Hospital in designing and implementing appropriate programs for the chronically mentally ill for which there are payors, with particular emphasis on Medicare." *Id.* The agreement was subject to amendment in "the event Medicare, Medicaid, any third party payor, or any other Federal, State, or local laws, rules, regulations or interpretations" substantially changed the method or amount of reimbursement or payment for services under the agreement. *Id.* Dr. Palazzo was required to make her records available to the Secretary of Health and Human Services and the Comptroller General of the Government Accounting Office and to comply with "all applicable provisions of federal, state, local and other laws, ordinances, and government rules and regulations, including without limitation the Medicare and Medicaid Anti-Fraud and Abuse or Anti-Kickback Amendments to the Social Security Act. . . ." *Id.*

Accordingly, the superseding indictment is sufficient to allege the crime charged and to permit the

defendant to prepare a defense. The motion to dismiss counts 28-40 of the superseding indictment is denied.

D. Motion to strike surplusage

Dr. Palazzo contends that the following paragraphs should be stricken from the superseding indictment as surplusage:[9]

> 28. It was further part of the scheme and artifice to defraud that Palazzo exercised control over the lives of certain psychiatric patients by having them in group homes over which she had ownership, control or influence. The defendant also maintained frequent orders for home health services even though she was allegedly seeing the patients on a daily basis. When the defendant became affiliated with Touro, she eventually moved her patients to "Touro at Home," Touro's home health agency, which was required to hire two nurses who had been with the defendant's patients for years.

---

[9] The motion to strike surplusage was based on the original indictment and filed prior to the return of the superseding indictment. The court addresses the language as it appears in the superseding indictment because the defendant's argument concerns striking all references to the subject matter of the group homes as a means for Dr. Palazzo to exercise control over the patients, rather than the specific language of either the indictment or the superseding indictment.

"The fifth amendment guarantees a criminal defendant the right to be tried only on charges presented in an indictment returned by a grand jury." *United States v. Ramirez,* 670 F.2d 27, 28 (5th Cir. 1982). Rule 7(d) authorizes the court to "strike surplusage from the indictment or information" upon the defendant's motion. Fed. R. Crim. Pro. 7(d). "For language to be struck from an indictment, it must be irrelevant, inflammatory, and prejudicial." *United States v. Graves,* 5 F.3d 1546, 1550 (5th Cir. 1993). Because the standard is exacting, a court rarely grants such a motion. *See* Wright, Federal Practice and Procedure: Criminal 3d § 127 at 639 (citing *United States v. Hedgepeth,* 434 F.3d 609, 611 (3rd Cir. 2006) ("Motions to strike surplusage are rarely granted.")).

The government intends to prove the elements of the offense of health care fraud by evidence that there was a scheme to defraud a health benefit program. The specific allegation that one of the ways Dr. Palazzo accomplished that scheme was to control her patients' attendance at the PHP through living arrangements in a group home setting. The language Dr. Palazzo seeks to strike concerns the manner in which Dr. Palazzo maintained control over the patients. The language is relevant to the charge and describes in part how Dr. Palazzo was able to accomplish the alleged scheme to defraud. Accordingly, the motion to strike surplusage is denied.

New Orleans, Louisiana, this 24th day of October, 2007.

/s/ Mary Ann Vial Lemmon
MARY ANN VIAL LEMMON
UNITED STATES
DISTRICT JUDGE

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 07-31119

UNITED STATES OF AMERICA
Plaintiff-Appellant

v.

MARIA CARMEN PALAZZO, MD, PhD, MMM
Defendant-Appellee

Appeal from the United States District Court
for the Eastern District of Louisiana
at New Orleans

ON PETITION FOR REHEARING EN BANC

(Filed Mar. 20, 2009)

(Opinion ___, 5 Cir., ___, ___ F.3d ___)

Before Judges REAVLEY, STEWART, and OWEN, Circuit Judges.

PER CURIAM:

(X) Treating the Petition for Rehearing En Banc as a Petition for Panel Rehearing, the Petition for Panel Rehearing is DENIED. No member of the panel nor judge in regular active service of the court having requested that the court be polled on Rehearing En

Banc (FED. R. APP. P. and 5th CIR. R. 35), the Petition for Rehearing En Banc is DENIED.

( ) Treating the Petition for Rehearing En Banc as a Petition for Panel Rehearing, the Petition for Panel Rehearing is DENIED. The court having been polled at the request of one of the members of the court and a majority of the judges who are in regular active service and not disqualified not having voted in favor (FED. R. APP. P. and 5th CIR. R. 35), the Petition for Rehearing En Banc is DENIED.

ENTERED FOR THE COURT:

/s/ Carl E. Stewart
United States Circuit Judge

Supreme Court, U.S.
FILED
AUG 13 2009
OFFICE OF THE CLERK

(2)

No. 08-1536

In the Supreme Court of the United States

MARIA CARMEN PALAZZO, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

ELENA KAGAN
Solicitor General
Counsel of Record
TONY WEST
Assistant Attorney General
DOUGLAS N. LETTER
STEVEN I. FRANK
Attorneys
Department of Justice
Washington, D.C. 20530
(202) 514-2217

QUESTION PRESENTED

Whether 21 U.S.C. 355(i) authorizes the Secretary of Health and Human Services to promulgate record-keeping obligations for clinical investigators in trials of new drugs, the violation of which can be punished with criminal sanctions under 21 U.S.C. 331(e) and 333(a).

TABLE OF CONTENTS

Page

Opinions below 1
Jurisdiction 1
Statement 1
Argument 4
Conclusion 8

TABLE OF AUTHORITIES

Cases:

Hamilton-Brown Shoe Co. v. *Wolf Bros.*, 240 U.S. 251 (1916) 5
Touby v. *United States*, 500 U.S. 160 (1991) 7
United States v. *Garfinkel*, 29 F.3d 451 (8th Cir. 1994) ... 6
United States v. *Smith*, 740 F.2d 734 (9th Cir. 1984) 6, 7, 8
VMI v. *United States*, 508 U.S. 946 (1993) 5

Statutes and regulations:

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* 2
21 U.S.C. 331(e) 2, 3, 4, 5, 6
21 U.S.C. 333(a) 2, 3, 4, 5
21 U.S.C. 355 2
21 U.S.C. 355(i) 2, 3, 4, 5, 6, 7
21 U.S.C. 355(i)(1) 2, 5
21 U.S.C. 355(i)(4) 6
18 U.S.C. 1347 ..... 1, 3
21 U.S.C. 811(h)(1) 7

Regulations—Continued: Page

21 C.F.R.:
Section 312.1(a)(12) (1985) 8
Section 312.1(a)(13) (1985) 8
Sections 312.60-312.70 (1987) 8
Section 312.62 ..... 2, 6
Section 312.62(b) 2, 3

Miscellaneous:

H.R. Rep. No. 2464, 87th Cong., 2d Sess. (1962) 6

In the Supreme Court of the United States

No. 08-1536

MARIA CARMEN PALAZZO, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-18) is reported at 558 F.3d 400. The opinion of the district court (Pet. App. 19-45) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 6, 2009. A petition for rehearing was denied on March 20, 2009 (Pet. App. 46-47). The petition for a writ of certiorari was filed on June 10, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

A grand jury in the Eastern District of Louisiana returned an indictment charging petitioner with 40 counts of health-care fraud, in violation of 18 U.S.C. 1347, and 15 counts of violating the record-keeping re-

quirements of the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, in violation of 21 U.S.C. 331(e) and 333(a). The district court granted petitioner's motion to dismiss the record-keeping counts. The court of appeals reversed and remanded. Pet. App. 1-18.

1. Before any drug may be sold in the United States, the FDCA requires that the Food and Drug Administration (FDA) determine whether it is safe and effective for its intended use. 21 U.S.C. 355. Because the Act prohibits the distribution of an unapproved drug for human use, but also recognizes that pre-approval human studies are necessary to provide the clinical data on which FDA bases approval decisions, the Act allows for the testing of new drugs as part of FDA's drug-approval process. Specifically, 21 U.S.C. 355(i) directs the Secretary of Health and Human Services (Secretary) to issue regulations governing investigatory drug trials. Under Section 355(i), the Secretary must "promulgate regulations for exempting from" the blanket prohibition against the distribution of unapproved drugs, certain distributions of "drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." 21 U.S.C. 355(i)(1). The statute further provides that the regulations may impose "conditions relating to the protection of the public health" on such exemptions. *Ibid.* Based on that authority, the Secretary has adopted 21 C.F.R. 312.62, which, among other things, requires clinical investigators "to prepare and maintain adequate and accurate case histories" on each individual administered the drug or employed as a control in the investigation. 21 C.F.R. 312.62(b).

2. Petitioner was a psychiatrist who was hired by a drug manufacturer to carry out clinical studies in order to evaluate the efficacy and safety of Paxil, a prescription drug, for children and adolescents with obsessive-compulsive disorder. Superseding Indictment 1, 17-18. Petitioner was paid according to the number of children she enrolled in the study. Superseding Indictment 18. According to the indictment, petitioner violated the record-keeping requirements of 21 C.F.R. 312.62(b) by falsifying case histories and diagnoses of children who were not qualified to participate in the study because they did not in fact suffer from obsessive-compulsive disorder. *Id.* at 20-24. In so doing, she made the patients falsely appear to be eligible for the clinical trial. *Ibid.*

3. A grand jury in the Eastern District of Louisiana returned an indictment charging petitioner with 40 counts of health-care fraud, in violation of 18 U.S.C. 1347, and 15 counts of violating the record-keeping requirements of the FDCA, in violation of 21 U.S.C. 331(e) and 333(a). Pet. App. 4. Section 331(e) makes it a criminal offense to "fail[] to establish or maintain any record * * * required under section * * * 355(i)." 21 U.S.C. 331(e); see 21 U.S.C. 333(a).

Petitioner moved to dismiss the record-keeping counts, and the district court granted the motion. Pet. App. 19-45. According to the court, Section 355(i) "does not authorize criminal penalties for violations by clinical investigators in maintaining adequate and accurate records." *Id.* at 35-36.

4. The court of appeals reversed and remanded. Pet. App. 1-18. Petitioner argued that Section 355(i) "only provides criminal sanctions for manufacturers and sponsors of clinical investigational studies," not for those

conducting the investigations. *Id.* at 12. The court of appeals rejected that argument, explaining that "Section 355(i) allows the Secretary to establish reporting requirements, and the Secretary promulgated regulations specific to investigators in 21 C.F.R. § 312.62(b)." *Id.* at 16. The court observed that those regulations "are properly considered to be 'required' reporting and record-keeping requirements under § 331(e)." *Ibid.* And, the court noted, Section 333(a) provides for criminal penalties for violations of requirements under Section 331(e). *Ibid.* In reaching that conclusion, the court emphasized that petitioner "conceded that § 355(i) provides the FDA with unambiguous authority to promulgate regulations requiring clinical investigators to adhere to specific record-keeping and reporting requirements." *Id.* at 17. Nothing in Section 331(e), the court continued, suggests "that it only serves to prohibit a failure to establish or maintain records and reports submitted directly to the Secretary." *Ibid.*[*]

ARGUMENT

Petitioner renews (Pet. 15-25) her claim that 21 U.S.C. 331(e) and 333(a) do not impose criminal liability on clinical investigators who violate FDA regulations adopted under 21 U.S.C. 355(i). The court of appeals correctly rejected that claim. Further review is not warranted.

1. As an initial matter, this Court's review is unwarranted at this time because the court of appeals reversed

---

[*] While the appeal was pending, petitioner was tried by a jury on the remaining counts of the indictment, except for one count that was dismissed on the motion of the government. The jury found petitioner guilty on all counts, and she was sentenced to 87 months of imprisonment. Judgment 1-2.

the dismissal of a portion of the indictment and remanded to the district court for a trial, so the case is still in an interlocutory posture. This Court routinely denies petitions by parties challenging interlocutory determinations that may be reviewed at the conclusion of the proceedings. See, *e.g.*, *VMI* v. *United States*, 508 U.S. 946 (1993) (Scalia, J., respecting denial of certiorari); *Hamilton-Brown Shoe Co.* v. *Wolf Bros.*, 240 U.S. 251, 258 (1916). That practice ensures that all of a defendant's claims will be consolidated and presented in a single petition. Here, the interests of judicial economy would be best served by denying review now and allowing petitioner to reassert her claims at the conclusion of the proceedings, if she still wishes to do so at that time.

2. The court of appeals correctly held that the conduct alleged in the indictment constitutes a criminal violation of the FDCA. Section 333(a) prescribes criminal penalties for "[a]ny person who violates a provision of section 331," and Section 331(e) prohibits "the failure to establish or maintain any record" required under Section 355(i). Petitioner has conceded that Section 355(i) "provides the FDA with unambiguous authority to promulgate regulations requiring clinical investigators to adhere to specific record-keeping and reporting requirements." Pet. App. 17. But she argues (Pet. 22-24) that violations of those requirements may be criminally punished only when they are committed by drug manufacturers or sponsors of investigations, and not by clinical investigators. That is incorrect.

Petitioner's argument is inconsistent with the plain language of Section 355(i)(1), which provides that the Secretary, in promulgating regulations exempting investigational drugs from the new-drug-approval requirements, may impose "other conditions relating to the pro-

tection of the public health." The Secretary has reasonably determined that the protection of the public health requires that clinical investigators keep adequate records relating to drug trials. See 21 C.F.R. 312.62; see also H.R. Rep. No. 2464, 87th Cong., 2d Sess. 9-10 (1962) (noting that, under Section 355(i), "the regulations may require, among other things * * * the establishment and maintenance of adequate records"). A violation of those record-keeping requirements—including one committed by a clinical investigator—is a "failure to establish or maintain any record * * * required under section * * * 355(i)," and it is therefore a criminal offense. 21 U.S.C. 331(e).

Petitioner relies (Pet. 23) on language in Section 355(i)(4) providing that "[n]othing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs." That provision is not relevant here, because 21 C.F.R. 312.62 does not require that investigators submit reports directly to the Secretary, but only that they prepare and maintain accurate records. Likewise, the indictment in this case does not allege that petitioner failed to submit reports to the Secretary. Instead, it alleges that she "failed to prepare and maintain records * * * on each individual administered the investigational drug or employed as a control in the investigation." Superseding Indictment 20.

3. The decision below is consistent with the result reached by the Eighth Circuit in *United States* v. *Garfinkel*, 29 F.3d 451 (1994), see Pet. App. 7-9 (describing *Garfinkel*), and any difference in rationale, see Pet. 18-19, would not warrant this Court's review. Petitioner asserts (Pet. 15-20) that this Court's review is necessary in order to resolve a conflict with the Ninth Circuit's

decision in *United States* v. *Smith*, 740 F.2d 734 (1984), but that claim is incorrect. In *Smith*, the court of appeals held that the FDCA does not "attach criminal liability to * * * clinical investigators" who fail to comply with regulations promulgated under Section 355(i). *Id.* at 737. The asserted conflict with *Smith* does not warrant review, however, because the issue does not appear to have arisen with any frequency in the 25 years since *Smith* was decided, and subsequent developments in the law suggest that the Ninth Circuit may reconsider its position if it is confronted with the issue again.

The court in *Smith* believed that the "general authorizing language" of Section 355(i) was "insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability," 740 F.2d at 738, but that reasoning has been undermined by this Court's more recent decision in *Touby* v. *United States*, 500 U.S. 160 (1991). In *Touby*, this Court upheld a criminal conviction for manufacturing a drug that the Attorney General, not Congress, had listed as a controlled substance. The governing statute authorized the Attorney General to list substances when doing so was "necessary to avoid an imminent hazard to the public safety." 21 U.S.C. 811(h)(1). The manufacturers of the drug argued that "Congress must * * * provide more specific guidance" when authorizing the issuance of regulations whose violation will be subject to criminal sanctions. *Touby*, 500 U.S. at 166. This Court rejected that argument, holding that the statutory language was adequate because it "meaningfully constrain[ed] the Attorney General's discretion to define criminal conduct." *Ibid.* Section 355(i)'s requirement that the Secretary's regulations pertain to "conditions relating to the protection of the public health" is similar to the "necessary to

avoid an imminent hazard to the public safety" standard upheld in *Touby*, so *Touby* essentially renders invalid the reasoning in *Smith*.

As an alternative basis for its decision, *Smith* emphasized that "the regulatory language [fell] short of imposing an explicit affirmative duty on the investigators to maintain accurate records." 740 F.2d at 738. The regulatory context has since changed. At the time, the Secretary's regulations required only that the sponsor of the investigation "obtain from each investigator * * * a signed statement" committing the investigator to keep accurate records. *Id.* at 738 n.4 (quoting 21 C.F.R. 312.1(a)(12) and (13) (1985)). After *Smith*, the FDA amended its regulations and added a series of new provisions devoted entirely to the responsibilities of clinical investigators and containing explicit record-keeping requirements. 21 C.F.R. 312.60-312.70 (1987). Those requirements alleviate the *Smith* court's concerns about the adequacy of notice. 740 F.2d at 738. Accordingly, *Smith*'s reasoning is inapplicable to the current regulatory regime.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

ELENA KAGAN
Solicitor General
TONY WEST
Assistant Attorney General
DOUGLAS N. LETTER
STEVEN I. FRANK
Attorneys

AUGUST 2009

No. 08-1536

Supreme Court, U.S.
FILED
AUG 24 2009
OFFICE OF THE CLERK

In The
Supreme Court of the United States

MARIA CARMEN PALAZZO, M.D., Ph.D., MMM,

Petitioner,

v.

THE UNITED STATES OF AMERICA,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

REPLY BRIEF FOR PETITIONER MARIA CARMEN PALAZZO

HERBERT V. LARSON, JR.
Counsel of Record
WILLIAM P. GIBBENS
SCHONEKAS, WINSBERG,
EVANS & MCGOEY, L.L.C.
650 Poydras Street, Suite 2105
New Orleans, Louisiana 70130
(504) 680-6050

Attorneys for Petitioner
Maria Carmen Palazzo

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
ARGUMENT	1
1. This Case Is Not In An Interlocutory Posture	2
2. The Opinion Of The Court Of Appeals Is Manifestly Erroneous And Conflicts With The Decisions Of This Court	4
CONCLUSION	8

TABLE OF AUTHORITIES

Page

CASES:

Serfass v. United States, 420 U.S. 377 (1975) 3

Touby v. United States, 500 U.S. 160 (1990) 2

United States v. Garfinkel, 29 F.3d 451 (8th Cir. 1994) 6, 7

United States v. Helstoski, 442 U.S. 477 (1979) 3

United States v. Palazzo, 558 F.3d 400 (5th Cir. 2009) 7

United States v. Smith, 740 F.2d 734 (9th Cir. 1984) 5, 7

STATUTES AND REGULATIONS:

21 U.S.C. § 355 .....1, 4

21 U.S.C. § 355(i) 7

21 C.F.R. § 312.62 .....4, 6

New Drug, Antibiotic, and Biologic Drug Product Regulations, 52 Fed. Reg. 8798, 8827 (Mar. 19, 1987) (to be codified as 21 C.F.R. pts. 312, 314, 511, and 514) 6

ARGUMENT

In 1962, when Congress enacted the statute at issue, 21 U.S.C. § 355, it placed very clear limits on the regulatory authority of the FDA. Moreover, Congress decided that *it*, not the FDA, would retain the power to determine precisely which conduct under the statute would be criminal – by limiting the delegation of power to the FDA to the creation of *exemptions* from the blanket prohibition against the distribution of unapproved drugs. In 1962 it was clear – at least to Congress – that the FDA had no power whatsoever to create criminally-enforceable regulations regarding physician clinical investigators.

This Congressional limitation has been under siege by the FDA for 25 of the last 47 years. During that time, the FDA has flatly ignored one circuit court of appeals, it has persuaded another to apply the *Chevron* deference doctrine in a criminal case, and most recently, in this proceeding, it convinced a court of appeals that there is no difference between a civil regulation and one enforceable by criminal sanctions.

Respondent suggests that the usurpation of Congressional power by the FDA should not be disturbed by this Court, because: (1) this case is "still in an interlocutory posture," and thus "the interests of judicial economy would be best served by denying review now and allowing petitioner to reassert her claims at the conclusions of the proceedings, if she still wishes to do so at that time[;]" and (2) the court of appeals "correctly held that the conduct alleged in

the indictment constitutes a criminal violation of the FDCA." Resp't Opp'n 5.

With regard to the first contention, Respondent is simply in error – as to both the procedural posture of the case and the interests of judicial economy. With regard to the second, Respondent, like the Fifth Circuit, finds it necessary to omit the words "exempting" and "exemption" from its reading of the statute in order to fashion a coherent delegation argument. Worse, the remainder of Respondent's argument rests on the dubious proposition that the phrase "conditions relating to the protection of the public health" provides constitutionally adequate guidance for the creation of criminally-enforceable regulations. Resp't Opp'n 7.

In short, Respondent fails to rebut the compelling reasons for granting review in this proceeding: (1) the divided opinions of the courts of appeals on this issue; (2) the Fifth and Eight Circuits' misapplication of *Touby v. United States*, 500 U.S. 160 (1990); and (3) the national significance of permitting the FDA to exercise direct criminal regulatory power over physicians conducting clinical trials. The Petition for the Writ of Certiorari should be granted.

1. This Case Is Not In An Interlocutory Posture.

When the district court dismissed the 15 counts alleging violations of the FDCA, the Government elected to do two things: (1) it filed a notice of appeal

on the dismissed counts; and (2) it proceeded to trial on the remaining counts of the superseding indictment. In effect, the Government created two separate prosecutions. On the latter, Petitioner stood trial, was convicted, and sentenced. Her appeal from that conviction is now before the Fifth Circuit as proceeding No. 09-30039. Accordingly, Respondent can only be suggesting that this matter is "interlocutory" because Petitioner has not yet stood trial on these specific charges.

Recognizing that in many instances it is fundamentally unfair to compel a petitioner to stand trial on criminal charges of highly questionable legality, this Court has not hesitated to grant certiorari in procedurally analogous, if not identical situations. *See, e.g., United States v. Helstoski*, 442 U.S. 477 (1979); *Serfass v. United States*, 420 U.S. 377 (1975). There is every reason to do so in this case.

Respondent would have Petitioner stand trial (again); and if convicted,[1] take an appeal to the Fifth Circuit – an appeal whose outcome is a foregone conclusion. Then, following that second adverse decision from the Fifth Circuit, Respondent would require Petitioner to file a second petition for a writ of

---

[1] Ironically, if Petitioner were to be acquitted at her trial, Respondent would still "win." Respondent's view that the statute permits it to enact criminally-enforceable regulations governing physicians would remain the law of the Fifth Circuit, and that court's ruling would be unchallengeable by the only party with standing to do so – Petitioner.

certiorari – all to present the very issues that are now squarely before the Court. If this is judicial economy, as Respondent suggests, more of it will bring the federal courts to a halt.

2. The Opinion Of The Court Of Appeals Is Manifestly Erroneous And Conflicts With The Decisions Of This Court.

Petitioner does not dispute, and in fact conceded at oral argument in the Fifth Circuit that the FDA has the authority to create regulations – including the authority to create the specific regulation at issue: 21 C.F.R. § 312.62. However, both Respondent and the Fifth Circuit persist in ignoring the vast difference between a civil regulation that compels physician record keeping on pain of the loss of an exemption from the FDA's blanket prohibition against the distribution of unapproved drugs, and a criminal regulation that can put a violator in federal prison for five years.

The intent of Congress could not have been plainer: not once, but twice, 21 U.S.C. § 355 specifically tied the promulgation of regulations by the Secretary to *exemptions*. Respondent ignores this unambiguous language.

Worse, although both Respondent and the Fifth Circuit concede that on its face 21 U.S.C. § 355 does not apply to clinical investigators, they treat this deliberate omission by Congress as a mere inconvenience. Instead of being guided by the [Congressional]

statute, both chose to ground the authority for the criminal prosecutions in a subsequent [administrative] regulation.

This lack of Congressional authority is precisely why the Ninth Circuit, in *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984) flatly rejected the FDA's attempt to criminalize inaccurate record keeping by a clinical investigator. As in this case, the FDA claimed the right to criminally prosecute under the statute's general regulatory authority, "which allows the Secretary to establish 'other conditions relating to the protection of public health.'" *Id.* at 737.

Significantly, the Ninth Circuit rejected this argument on two grounds: first, "[s]uch general authorizing language is insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability[;]" and second, " . . . even if Congress had provided standards for extending the recordkeeping requirement to investigators by regulation, the regulatory language falls short of imposing an explicit affirmative duty on the investigators to maintain accurate records." *Id.*

As noted by Respondent, after *Smith*, the FDA amended its regulations. Resp't Opp'n 8. What Respondent fails to mention is that when it did so, the FDA deliberately ignored the first half of the holding in *Smith*:

> FDA recognizes that some may view the decision by the Ninth Circuit in the [sic] *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984),

> which involved criminal charges against a clinical investigator, as raising questions about the agency's authority to promulgate enforceable regulations on the obligations of clinical investigators. **After considering the court's opinion, FDA concludes that it has ample authority to issue such regulations.**

New Drug, Antibiotic, and Biologic Drug Product Regulations, 52 Fed. Reg. 8798, 8827 (Mar. 19, 1987) (to be codified as 21 C.F.R. pts. 312, 314, 511, and 514) (emphasis added).

Thus, while the FDA may have "cured" the second problem noted by the Ninth Circuit – the absence of a regulation that imposed specific record-keeping requirements upon clinical investigators – by promulgating 21 C.F.R. § 312.62, the FDA never addressed the Ninth's Circuit's constitutional objection. Plainly, it felt no need to do so. Petitioner is hopeful, however, that this Court views such blatant disregard for the opinion of a court of appeals somewhat differently.

Notably, Respondent makes no effort to defend the Eighth Circuit's opinion in *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994), but simply notes that "[t]he decision below [in the Fifth Circuit] is consistent with the result reached by the Eighth Circuit . . . and any difference in rationale . . . would not warrant this Court's review." Resp't Opp'n 6. To the contrary, there is much more at stake than a difference in rationale. What is before the Court are

two deeply flawed opinions that rely on plainly erroneous readings of the law.

As noted in Petitioner's original brief, the Eighth Circuit mistakenly relied upon the *Chevron* deference rule to reach its result in *Garfinkel*. The FDA made the very same deference arguments to the Fifth Circuit in this case. In fact, it was represented by the same attorney who represented it in *Garfinkel*. While the Fifth Circuit did not rely on the *Chevron* doctrine in this case, it made it clear that it would do so, if the "parties disputed whether § 355(i) *authorized* the FDA regulations at issue in this case. . . ." *United States v. Palazzo*, 558 F.3d 400, 405 (5th Cir. 2009). Oddly enough, that is precisely what Petitioner believed she was doing by arguing that the FDA did not have the authority to issue criminally-enforceable regulations governing clinical investigators. Nevertheless, it is apparent that review by this Court is necessary to prevent the courts of appeals from applying the *Chevron* deference rule in criminal cases.

Given these significant concerns, it is not true that the precise "issue [presented by this case] does not appear to have arisen with any frequency in the 25 years since *Smith* was decided. . . ." Resp't Opp'n 7. In one sense, it has arisen every day since the FDA decided in 1987 that it actually possessed the authority that *Smith* denied it. And from *Palazzo* forward, the issue will become a daily factor in the life of all clinical investigators, who now face federal

criminal prosecution for failing to keep "accurate records" – whatever that means.

CONCLUSION

The Petition for a Writ of Certiorari should be granted.

New Orleans, Louisiana, this 24th day of August, 2009.

Respectfully submitted,

HERBERT V. LARSON, JR.
Counsel of Record
WILLIAM P. GIBBENS
SCHONEKAS, WINSBERG,
EVANS & MCGOEY, L.L.C.
650 Poydras Street, Suite 2105
New Orleans, Louisiana 70130
(504) 680-6050

Attorneys for Petitioner
Maria Carmen Palazzo